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FEB 10 2003
PATENT & TRADEMARK OFFICE

RPP:135F US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Molly F. Kulesz-Martin	Art Unit:	1642
Serial No:	08/811,361	Confirmation No:	1038
Filed:	March 4, 1997		
Examiner:	C. Yaen		
For:	p53as PROTEIN AND ANTIBODY THEREFOR		

I certify that this **REQUEST** is being deposited on, **January 31, 2003** with the U.S. Postal Service as first class mail addressed to Commissioner of Patents and Trademarks, Washington, D.C. 20231

Michael L. Dunn
Registration No. 25,330

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REQUEST FOR RECONSIDERATION

The Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Responsive to the official action of December 31, 2002, the Examiner is requested to reconsider the rejection and to allow the pending claim.

The Examiner has objected to claim 11, the only pending claim, under 35U.S.C. 101 for lack of utility. With due respect to the Examiner, this rejection is completely inappropriate and should be withdrawn.

The specification is directed to a peptide that permits p53as to be distinguished from p53. That is sufficient utility under 35 U.S.C. 101 all by itself. Since by definition p53 and p53as differ at the carboxy terminal sequences, any antibody that reacts with p53 will also react with p53as unless the unique claimed carboxy terminal region is used to distinguish the different p53 forms. p53 and p53as differ in at least the fact that p53as lacks the negative regulatory domain of p53 and thus one studying p53 function or using p53 species in therapy would want to know

how much p53 vs. p53as is present. If there are additional differences it becomes even more important to distinguish these species. The Examiner's reliance upon "the same function as that of p53" for showing lack of utility seems misplaced. There is no doubt that p53 is different than p53as in that p53as lacks the negative regulatory domain of p53. The claimed peptide thus has clear utility in distinguishing the two species. If there are other differences it becomes even more important to be able to distinguish the species and this would add to utility of the claimed peptide rather than detract from it. It is thus clear that the claimed peptide has more than enough utility to meet the requirements of 35 U.S.C. 101 in being utilizable to distinguish p53 from p53as.

The Examiner further states that "The p53as protein claimed as stated in the specification has not been clearly reported and investigated at the time of filing." The Examiner is in error in a couple of respects. The specification clearly provides support showing that the claimed peptide can be used to distinguish p53 protein from p53as protein and the Examiner admits that functions of p53 have been well studied. Further, Hupp et al. cited in the specification clearly showed that truncation of p53 at the carboxy terminal end retained p53 function but eliminated the negative regulatory domain. The truncated p53 was thus always active. p53as similarly is missing the negative regulatory domain but can otherwise be expected to have essentially the same functions as p53 because it otherwise has the same sequence as p53 up to the point of truncation shown by Hupp et al. The specification in view of Hupp et al. and data presented in the specification thus predicts that result. The Examiner's attention is, for example, called to page 7 of the specification showing correlation between cancer cell expression and p53 and p53as. There could hardly be a better utility than cancer detection. Further, if subsequently

published documents verify such predictions, and they have, such documents may be considered as showing the veracity of the statements made in the specification. As a matter of law p53as thus need not have been completely studied at the time of filing if statements made are subsequently verified. The Patent Office has recognized this legal principle almost since its inception by permitting rule 132 affidavits presenting subsequent data verifying statements made in the specification. The Examiners attention is for example called to European publication EP 0 709 397 A1 on page 2 lines 21-25 "The presence of the p53as protein in tumor cells and antibodies for its detection has applications in basic research on cell growth and differentiation....The association with G2 suggests a functional role in G2 arrest and potential for gene therapy using the p53as coding sequence." The entire EP publication goes on to support utility. There are numerous other such publications. The rejection should be withdrawn.

In view of the foregoing, is asserted that all objections and rejections have been overcome and all claims are in condition for allowance, which action is courteously requested.

Respectfully submitted,

Dated: January 31, 2003

Michael L. Dunn
Attorney for Applicant(s)
Reg. No. 25,330
P.O.Box 10
Newfane, New York 14108
Telephone: (716) 433-1661

MLD/cah
cc: P. Reczek
J. Jurkowski
M. Kulesz-Martin